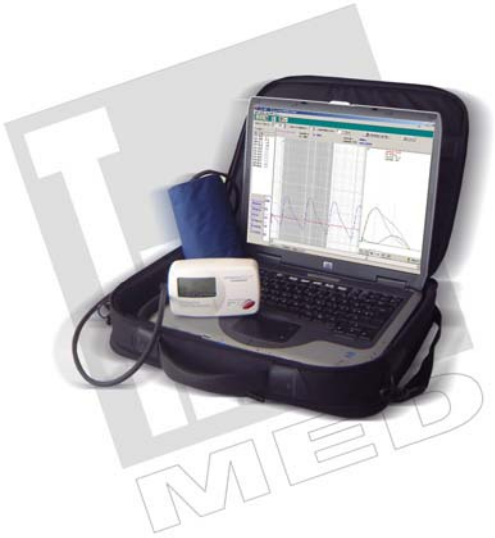
TensioMed Ltd.

User's manual

TensioClinic
TensioMed™ Arteriograph

and

TensioMed™
program



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TensioMed™ Arteriograph-5-01, v1.9

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1. Tensiomed™ Arteriograph

1.1. Appliance purpose and functions of the device

The TensioMed™ Arteriograph is a special device which can measure the arterial stiffness (augmentation index, aortic pulse wave velocity). It is patented and based on oscillometric theory.

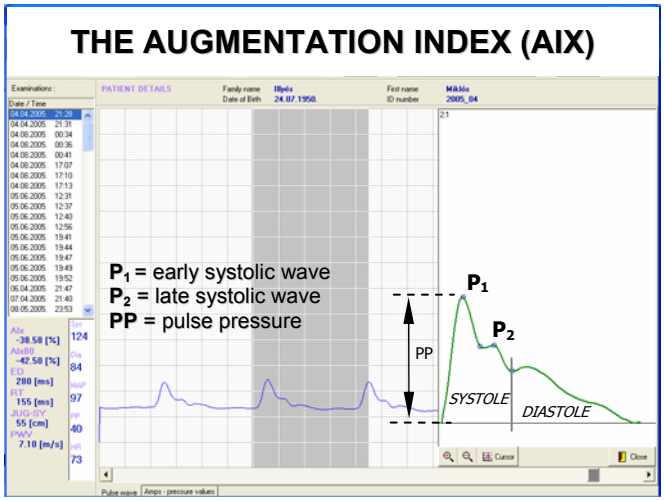
The importance of measuring the arterial stiffness

Limits of the stratification based on the classical cardiovascular risk factor.
The SCORE or Framingham analysis based on the classical risk factors (age, sex, smoking, cholesterol, systolic blood pressure) is very effective at population level, but the insecurance determination of the concrete individual person is not so correct. It is proved among other things the „Coronary Heart Disease" publication of the "White Paper" serial from 1998 which was made by the John Hopkins Hospital (USA). It says that just 40% of the people who had heart disease had hypertonic and increased cholesterol. At the all day practice is known the Churcill-effect (over weighted, smoker, poor in move) people with cumulative risk over the age of 90, and unfortunately many times the opposition is also happens when young at first sight "healthy", people had a fatal cardiovascular event.

In consideration of that the classical risk factors had just indirect information about the atherosclerotic procedures which causes the CV events. Therefore come the want that the property of the artery could be examined direct by non-invasive methods. With the help of this method, we could improve the CV risk estimation and we could detect in the subclinical stage the arteriosclerosis.

The arterial stiffness
Among numerous of methods spread mostly the determination of the arterial stiffness. It is the measurement of the augmentation index (Aix) and the pulse wave velocity (PWV). The reviews of the hundreds of publications in the subject we could now without any doubt say that the intensify of the vascular arterial stiffness, namely the increase of the augmentation index and the enhancement of the arterial pulse wave velocity overtake the appearance of the arteriosclerosis and these parameters strong, self-dependent, independent from the classical risk and they could forecast the CV disease which was caused by arteriosclerosis.

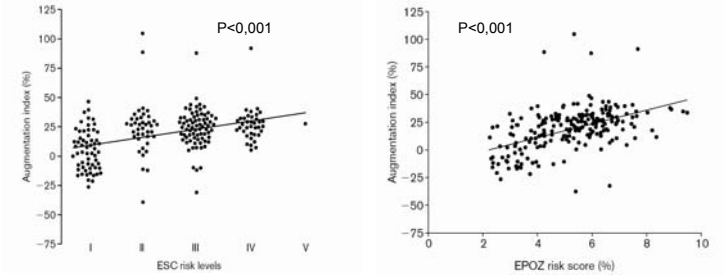
The importance of the augmentation index in the definition of the CV risk.
The definition of the augmentation index: it is the two systolic peak wave on the pulse wave, so it is a ratio in percent (PP=Pulse pressure) which is the difference of the earlier systolic wave (P_1) which was caused directly by the ejection and the second reflected (lately systolic) wave (P_2).



According to the meaning if P2 is smaller than P1 the value of the augmentation index will be negative. In the opposite so when the periferial resistance increasing, this value rising. The Aix value beside of the arterial flexibility primarily the resistance of the actual peripheral vascular of the resistance veins (little arterials, arterioles) defines (TPR). The less the TPR the less the Aix and reversely.

Evidences prove that the rose Aix value and the classical CV risk factors have a strong relationship.

Augmentation index is a marker of classical CV risk factors



Nürnberger et al.: J Hypertens 2002;20:2407

It is more major than the things which have been upper written that the ***augmentation index independently from the classical risk factors disposes of prognostic power*** so the lack of those is a forecast of the CV events. The examinations of Chirinos and his colleagues on patients with coronal arterial proved that the increasing of the Aix by 10% increasing the risk of CV death by 28%.

Relation between AIx and CV events in CHD

	Corrected relative risk	Variables int he model
Aix (10% increase)	**1,28 (1,09-1,50)**	**Age, height, ACE-i, BB, statin, MAP, HR, EF, diabetes, smoking, CRP, CHF, severity of CHD**

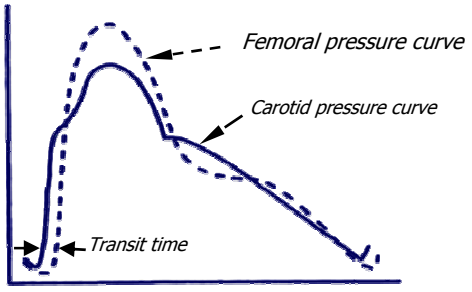
AIx is a strong and independent risk factor of adverse cardiovascular outcomes!

The importance of the pulse wave velocity (PVW) as prognostic value of the CV risk

The PVW of the aorta could be measured as: detected the transit time of two points (mostly the artery carotis and the artery femoralis) of the pulse wave which was created by the ejected systolic volume. Than the distance of that two detected points to be located by measuring. After it applicable this formula (v=s/t) and we could get the pulse wave velocity in m/s dimension.

Caution this is not a flow (current)! The physic entity that we measure is the pulse wave velocity which is significantly influenced by the elastic properties of the aortic wall. The PVWao in the human aorta is 4-16 m/s depend on the age, to be more exact it is depend on the damage of the aorta wall structure, while the dimension of the current is cm/s so it is slower by an order of magnitude.

Aortic PWV



$V = s/t$ $\quad PWV\ (m/s) = \frac{Measuring\ sites\ distance}{Transit\ time}$

As the augmentation index alike the aorta PVW is proven self-sufficing, independent predictor of the CV mortality.

In Circulation (February 2006 edition) there was a hard voice paragraph (CV mortality, fatal and non-fatal coronary heart disease) from William Hunsen and his collaborators which proved with a long term (9.4 years) following study (1600 patients involved) that **the increasing of the aorta pulse wave velocity prognosticate the disadvantageous cardio vascular outcome over the efficiency of the traditional risk factors and independent from them.** This correlation staid significant even than if we supplement the classical risk factors in the multi-variance analysis with 24 hours long ambulant blood pressure monitoring and they observed the daily average values.

GENERAL POPULATION STUDY (Denmark):
1678 patients, between 40-70 years, 9,4 years follow up endpoints: CV mortality, fatal and non-fatal CHD

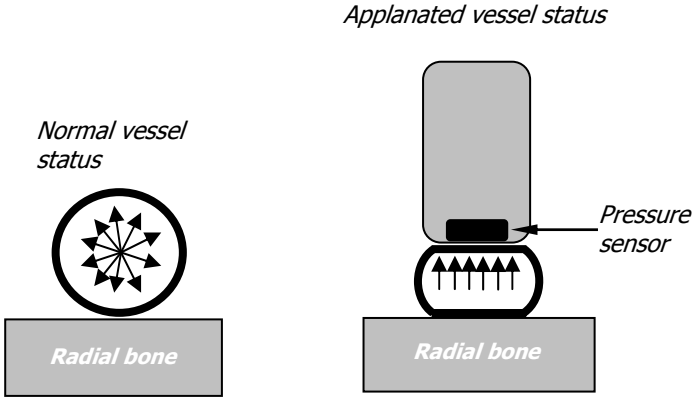
AORTIC PWV predicts cardiovascular outcomes above and beyond traditional risk factors, including 24h MAP (ABPM)

Willum-Hansen T. et al:
Circulation, 2006 Feb 7; 113(5) :664-70

The measurement of the arterial stiffness

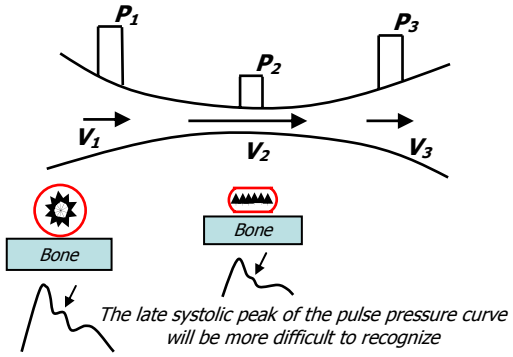
The measurement of the augmentation index(Aix) with applanation tonometry (piezometry)
The augmentation index with non-invasive method was measured mostly with applanation tonometry. The examination of the Aix: on the radial (rarely brachial, carotis) artery a pressure meter is taken, whereby the artery is a little bit compressed, flattened, so applanated this cause that the field lines in the vein will be parallel with the pressure sensor, so we can feel the pulse wave. (can be seen on the figure).

Applanation tonometry

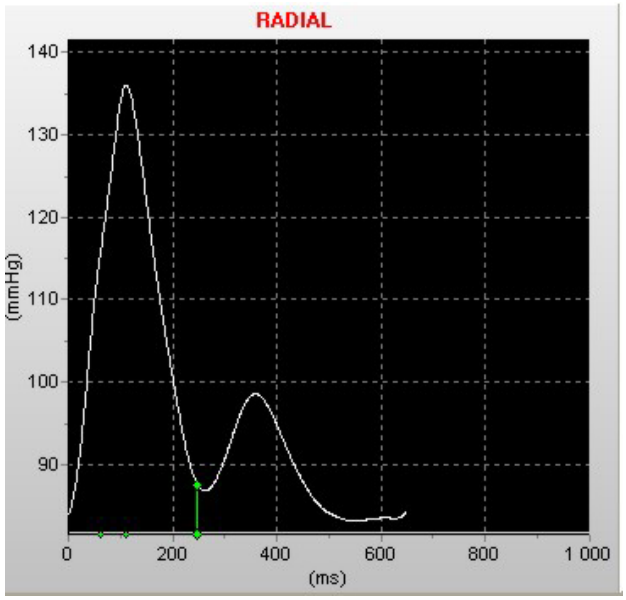


Whereas the method is wide spread but there aren't any publication which mentioned this measuring theoretical problem that occurs during the examination. The applanation of the artery is alike the Bernoulli-principle which says that as small as the diameter of a tube so big is the speed of moving in the stricture, while the pressure in the tube decreases.

Effect of the Bernoulli's principle on the applanation tonometry



As you can see in the upper picture this effect makes problems by measuring the Aix, while it makes difficulties on the detection of the systolic wave peaks. At the applanated vein the accelerated flow makes decompression, ergo makes smaller amplitudes, so one part of the measurement with applanation tonometry couldn't be detect the lately systolic wave peak, so therefore we couldn't determine the Aix either.

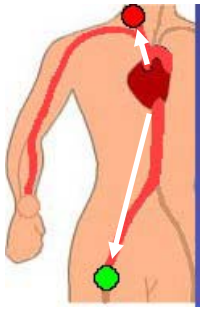


Couldn't be detect the lately systolic wave peak (reflected P_2)

The measurement of the aorta pulse wave velocity (PWVao)

Hitherto the measurement of the non-invasive PWV happened as the routine: we take to the artery carotis and to the femoralis a pressure detector and we measure the time between the appearance of the carotis pulse and the femoralis pulse, as well as the distance between the two points. The speed measure like this is not real while the direction of propagation of the pulse wave created by the heart to the direction of the carotis respectively to the femoralis is opposite.

Difficulting in PWV measurement



The propagation of the pulse pressure is int he opposite direction from the heart to the sites of the measurement

By hard adventure to the clearance of fault didn't happen in some study (or didn't mention at the describe of the methods). In an other group of the investigations they tried to correct the mistake as they subtracted from the distance between the carotis and the femoralis the double distance between the jugulum sterni and the carotis. This method gives a little bit exacted result but it isn't perfect, while we must have known the distance betweem the aortic root and the measurement place on the carotis, but the correct determination of it in the actual practice unaccomplishable.

We can define from the possibilities to measuring the arterial stiffness with using applanation tonometry especially the PWVao are very elaborate, time-consuming and to take over this examination we need provided, special trained staff. This is the explanation that the importance of measuring the Aix and PVWao was known for a long time but in the routine clinical use wasn't wide spread in outland and in Hungary either. And the use of this application was mostly used in special laboratories, mainly for research purposes.

These were the precedents of that aimed basic research project that we had begun inside the National Research and Developmental Programs in 2001. The basic purpose of the researches was to find out if oscillometric signals collected during an oscillometric blood pressure measurement by a simple upper arm cuff carry any clinically useful information about arterial stiffness.

2001
CREATING A RESEARCH CONSORTIUM

Hungarian Academy of Sciences
Institute of Material Sciences
Semmelweis Medical University
Institute of Human Physiology
Semmelweis Medical University
1st Departement of Internal Medicine
St.Emeritus Hospital, Budapest
1st Departement of Internal Medicine
TensioMed
Consortium leader

The way and the principle of the method to born the Arteriograph
The basic purpose of the researches was to find out if oscillometric signals collected during an oscillometric blood pressure measurement by a simple upper arm cuff carry any clinically useful information about arterial stiffness. Before we couldn't find any information in the medical and in the technical patents descriptions.

During our work we collected the oscillometric pulse waves from 650 patients home during for months, that were forwarded with telemedicinal method to our computer headquarter. Thusly we collected a huge database with more than 1.5 million oscillometric pulse wave curves. With modern mathematical methods, called "data mining" we discovered that because of the pressure change in the cuff we had very heterogenic waves and they have clinical relevant information.

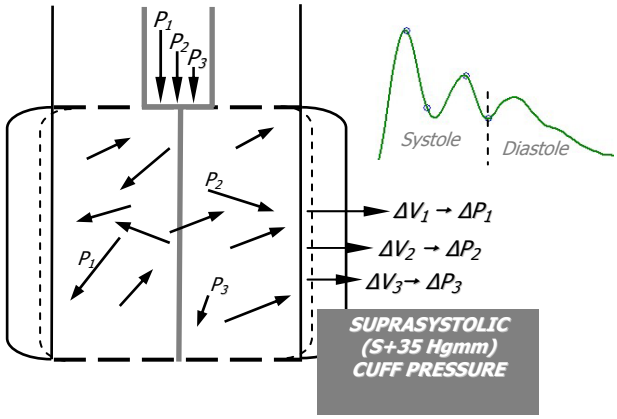
The additional investigation of the data's in our database and the parallel recorded clinical data's showed that the oscillation signs could be identified if the cuff has to be pressurized much over the systolic blood pressure (could be +100 Hgmm); whereas in this state there's a complete brachial artery occlusion and the arterial wall movement created by the flow is strangulated. In this special condition the cuff could be used as a very sensitive sensor if we assemble to the observation of the originated very weak signs an ultra sensitive pressure meter in the aspect of resolution and sampling.

The cuff can be used as a sensitive pressure sensor...
...if a very high-fidelity oscillometric tonometer is applied to receive the weak suprasystolic signals from the cuff

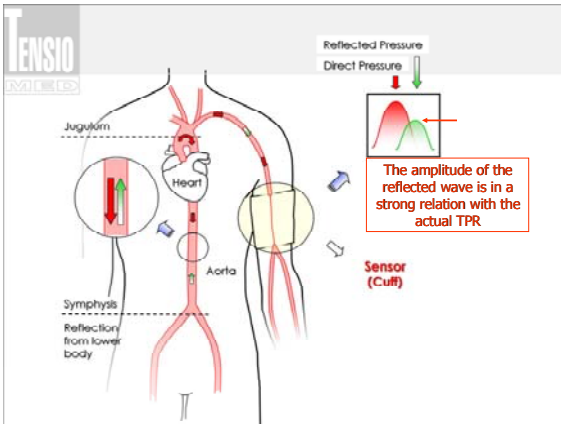
In this special "stop-flow" condition the pressure waves created by the left ventricle experimentally without any distortion reach the cuff because of the fact that fluid is

uncompressible, where they make a little compression at the cuff and they make generate volume and pressure changes, and we detect these changes.

THE PRINCIPLE OF OPERATION



On the upper figure it is good recognizable that the recorded pulse wave (on the right upper side of the picture) measured with the Arteriograph at suprasystolic pressure includes the earlier (P1) and the lately (P2) systolic wave. The valley caused by the closing of the aorta valve is good recognizable as well as the diastolic wave (P_3).

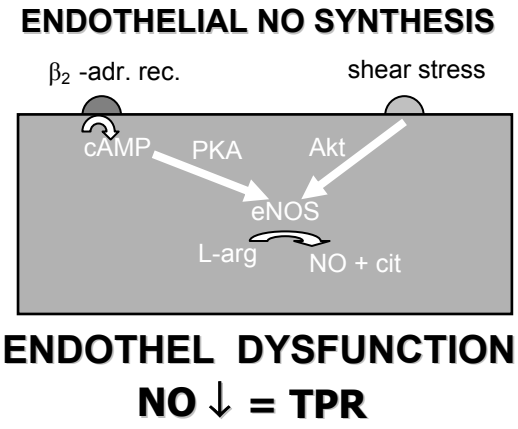


The upper figure illustrates the information content of the pulse waves recorded at suprasystolic pressure. Per the left ventricle to the aorta ejected systolic volume creates the direct wave, which reflected from the inferior body-half and creates the lately systolic (reflected) wave. The amplitude of the reflected wave is gear(plotted against) of the periphery vascular resistance.
The lower vascular resistance of the perfunded*** areas coming from the veins opening from the artery the lower will be the amplitude of the second (reflected) systolic wave and reversely. Calculated the time between the two wave peak, the traveling time of the outward and return journey could be defined. And if we measure the distance between the jugulum-symphysis (which is the same as by the invasive method, the distance between the aortic root and the bifurcation aorte) the pulse wave velocity is easily calculatable.

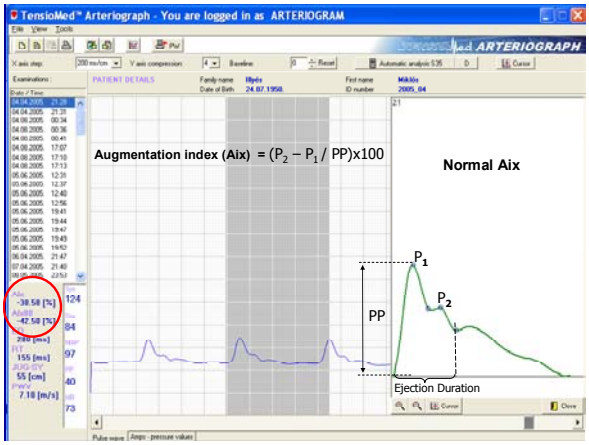
From the working principle of the Arteriograph we should pay attention that with these method – opposite to the applanation tonometry – by the Aix measurement the information loss coming from the Bernoulli-effect not exist. Furthermore at the calculation of PWVao we measure the real speed(velocity), after all the time between the first and the second systolic wave is connected to the distance between the aortic root and the bifurcation aorte.

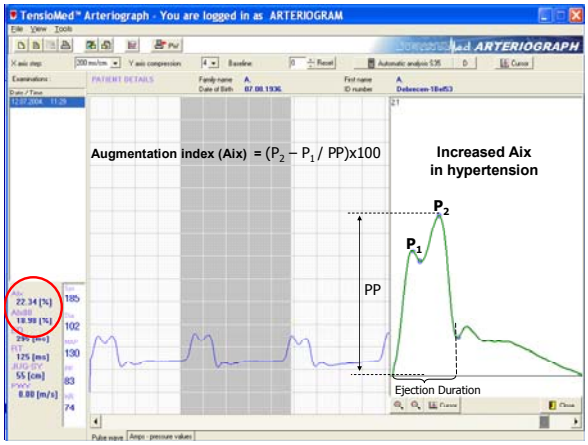
Thereafter ***the biggest advantage of the new oscillometric method is that the determination of parameters: Aix, PWVao, systolic and diastolic blood pressure, pulse number and other hermodinamical parameters is very easy and fast, it takes only one blood pressure measurement time.***

The Augmentation index(Aix) and the endithel dysfunction effected vascular resistance



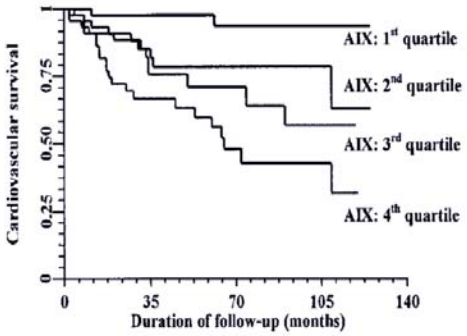
The endothel dysfunction is a complex procession, but from the clinical aspect it has an essential part, that the endothel dependent vasodilatation has a breakdown and accompanied by an arteriolic vasoconstriction and an increased total peripherial vascular resistanse (TPR). Therefore the amplitude of the second reflected (lately, systolic) wave and the augmentation pressure get larger, that is the reason why the value of the Aix is increased.
This process is conspicuous on the next two figures.
On the left side the normal on the right side the very high rise Aix can be seen, which caused the endothel/vascular dysfunction probably by the hypertension. The rose TPR signed by the chronic Aix. In the background probably the endothel (vascular) dysfunction stay.





The Augmentation index is in a strong and proven relation to the CV mortality.

Relation between AIx and CV survival

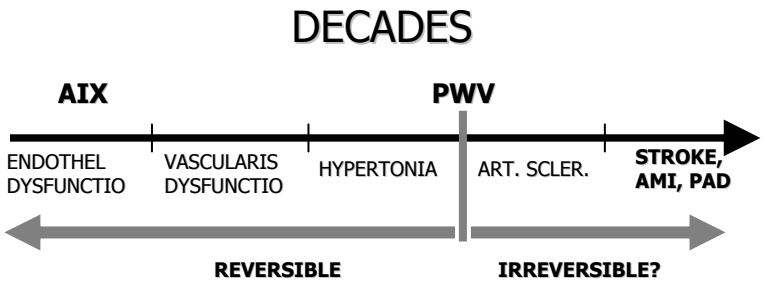


Hypertension 2001;38:434

In a following examination which was made with nephropathies whose have the highest augmentation index, so they belong to the chronic category. Among them 2/3 at the end of the examination period (average 6 years) died. With good survival possibilities have just the patients whose belong to the lowest quartile of the augmentation index.

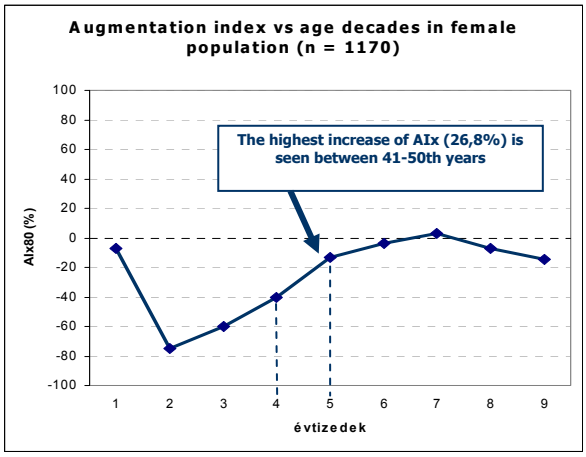
As far as we know the first stage of arteriosclerosis is the endothelial dysfunction, which leads to the structural remodelling of the small vessels, and then appear the vascular dysfunction, then hypertension and manifest arteriosclerosis develops. The last stage in this line and unfortunately the end of the life is a fatal cardiovascular event.

The genesis of arteriosclerosis



Both the endothel and the vascular dysfunction are characteristic of an increased peripherial vascular resistance (TPR), it can be assessed by measuring the augmentation index (Aix).
With the Arteriograph we can detect the arteriosclerosis in its earliest stage, endothel dysfunction phase, when most of the patients don't have any symptoms and complains. The importance of the detection of the preclinical atherosclerosis is that in this stage the patients have good chances to influence the procedure to a good way by changing the mode of live or by relatively simple, cost effective therapy.

The demonstration of the rose Aix which can denote to an accidental endhotel dysfunction is very important at the female population at the pre-menopausal age. It is because there is a statistical data that shows the cardiovascular death of the women is rising opposite to the men. The increasing cardiovascular risk caused by the menopause prove our examinations, too. We have made 1170 examinations with Arterigraph on women between the age 4-90 and after it calculated the average value of the Aix in age decades.



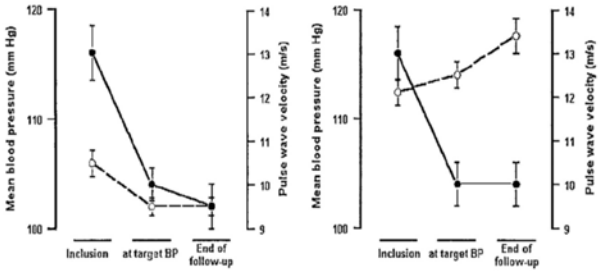
Illyés, M.: TensioMed Artérial Stiffness Centre, Budapest, Hungary

It could be seen that on the menarche period at the beginning occur a sharp Aix (peripheral resistance) decreasing, than in the following few decades a quite slow Aix increasing could be seen, in the next decades between 41-50 years, when the menopause evolves, a sharper, a 26,8% rising could be seen compared to the former decades. Probable the significant oestrogen rate changing is stay in the background, both the sharp vasodilatation at the menarche and the arteriolic vasoconstriction at the menopause. Nevertheless thinkable, how the menopause especially could increase the evolution of the endothelial dysfunction that expect the significant increasing of the Aix.

Aorta pulse wave velocity(PWVao), elasticity of the aorta wall and cardiovascular risk

The measuring of the aorta wave velocity (PWVao) firstly we get information about the aorta wall property. As far as the aorta wall is more rigid and inelastic as faster will be the pulse wave created by the left ventricle shooting through on the vein(artery). We also have to keep in mind, that if the blood volume rising in the aorta during a unit time (e.g. hypertonic, tachycardia, rising the cardiac output) the diameter of the aorta is rising, the tension of the wall increasing therefore the pulse wave velocity could be rise. Therefore the PWV has just in case prognostic value if the examination was in isobaric condition so in normotension.

Impact of Aortic Stiffness Attenuation on Survival of Patients in End-Stage Failure



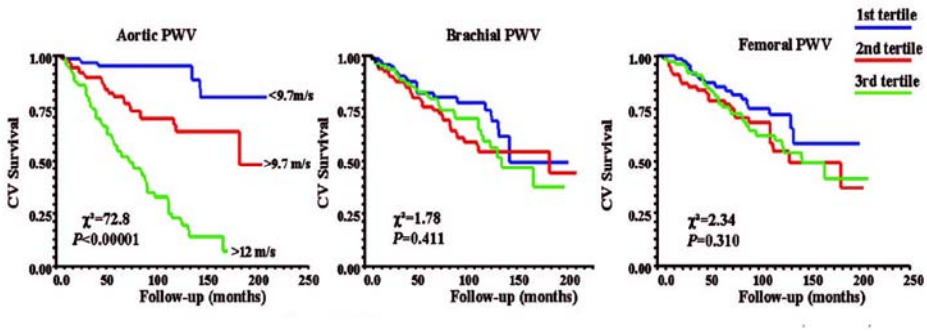
Circulation 2001;103:987

Guerin and his colleagues proved the upper wrote things in a very picturesque mode in the Circulation in 2001. In this investigation they successfully decreased the end stage nephrosis patients' blood pressure and during this they watched the changing of the PWVao. In the patient group where followed the blood pressure decreasing the PWVao has also decreased, the patients survived the following period.

At the other patients group where in spite of the smaller blood pressure the PVWao not decreased, unfortunately the entire investigated patients died during the following period which was in average 51 month. Which denote that opposite to the other group here the increased PWVao not the hypertension caused wall tension, but probably the morphological (atherosclerotic) injury of the vein.

For that very reason com the question, why did we make the PVW measurement on the aorta and why not for e.g. on the brachial or femoralis artery? The answer give us Pannier and his colleague's investigation, whose examined parallel the PVW of the brachial and femoral aorta on 305 patients with nephrosis. They followed the patients for an average 70 months to know in which vein why the PVW is in correlation with the heart and vascular death.

Increased PWV predicts CV mortality

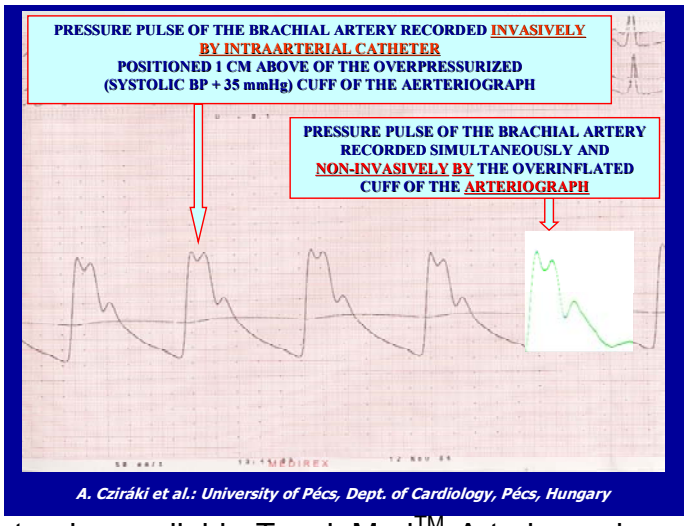


n = 305, 70 months follow up Hypertension 2005;45:596

They investigation's which results others proved, too. These investigations unequivocally proved that only the PVW measurements on the aorta have predictive value.

Validations

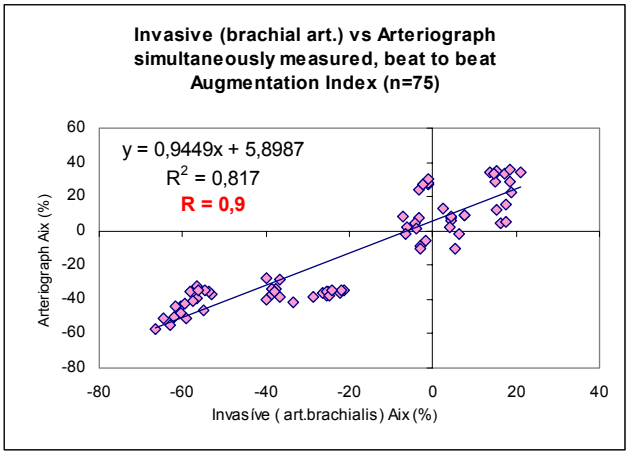
The most important question with all of the new methods is their reliability and accuracy considering the measured parameters. Usually non-invasive method is compared to another non-invasive method, which is not optimal. The real gold standard way, when the invasive, bloody measurement compare with the non-invasive method. However special thanks to the Cardiac Department of University of Pécs, Hungary, we had opportunities to compare TensioMed™ Arteriograph records with invasively recorded intrabrachial pressure curves to determine the AiX with both methods.


PRESSURE PULSE OF THE BRACHIAL ARTERY RECORDED INVASIVELY
BY INTRAARTERIAL CATHETER
POSITIONED 1 CM ABOVE OF THE OVERPRESSURIZED
(SYSTOLIC BP + 35 mmHg) CUFF OF THE AERTERIOGRAPH
PRESSURE PULSE OF THE BRACHIAL ARTERY
RECORDED SIMULTANEOUSLY AND
NON-INVASIVELY BY THE OVERINFLATED
CUFF OF THE ARTERIOGRAPH
A. Cziráki et al.: University of Pécs, Dept. of Cardiology, Pécs, Hungary

This picture illustrates how reliably TensioMed™ Arteriograph records the pressure curve non-invasively. It can be seen that after the series of the intrabrachial pulse pressure curves the last one is duplicated by the simultaneously controlled identical pulse recorded by TensioMed™ Arteriograph. The two (invasive and non-invasive) waves are identical.

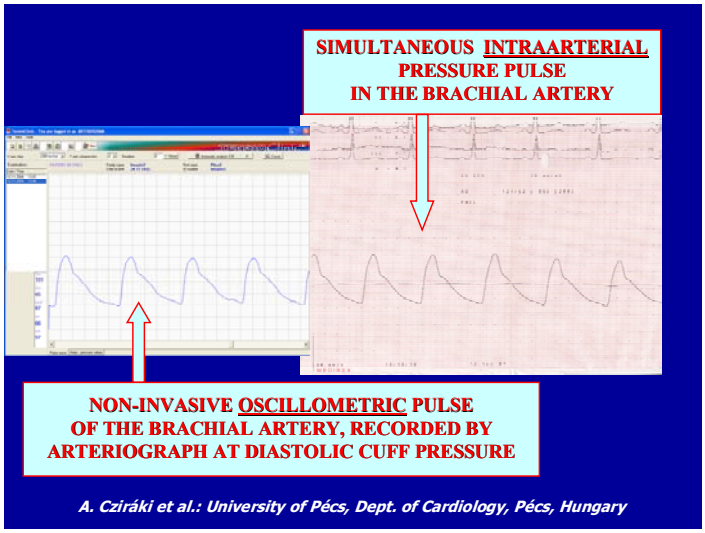
In a comparative study performed at Cardiac Department of Pécs University, Hungary 75 identical pulse curves were recorded by TensioMed™ Arteriograph and intrabrachial catheter simultaneously from 10 patients with different Aix ranges varying from -64% to +16,9%, so from the optimal to the pathological ranges.

On the previous figure the formerly seen identity in shape is proven statistically in relation to the Aix, because the R value turned to be more than 0,9, providing evidence, that the brachial artery AIx recorded either non-invasively by TensioMedTM Arteriograph or invasively by catheter is the same.



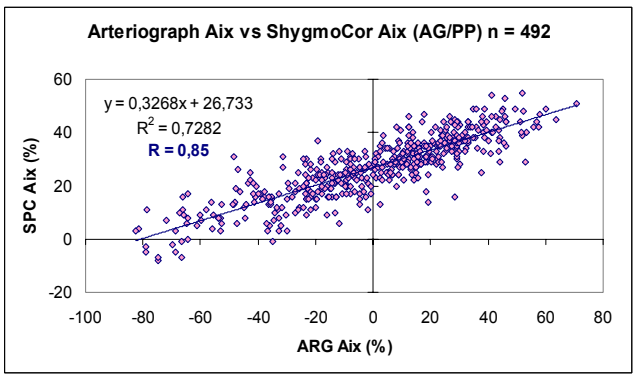
A. Cziráki et al.: University of Pécs, Dept. of Cardiology, Pécs, Hungary

The picture illustrates that agreement between invasive and non-invasive recordings exists not only in the suprasystolically recorded pulse curves, but also in case when the pulse trace is taken at the diastolic pressure of the cuff.


SIMULTANEOUS INTRAARTERIAL
PRESSURE PULSE
IN THE BRACHIAL ARTERY
NON-INVASIVE OSCILLOMETRIC PULSE
OF THE BRACHIAL ARTERY, RECORDED BY
ARTERIOGRAPH AT DIASTOLIC CUFF PRESSURE
A. Cziráki et al.: University of Pécs, Dept. of Cardiology, Pécs, Hungary

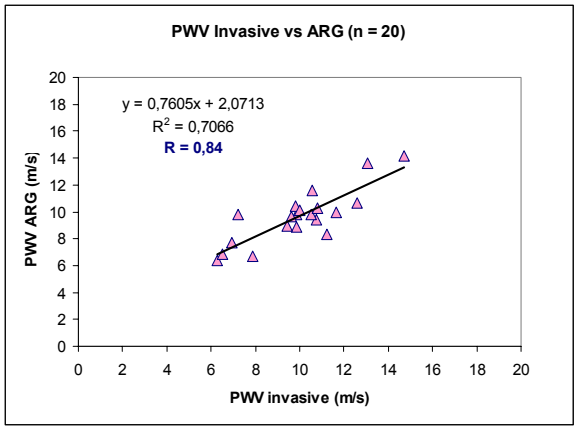
TensioMed™ Arteriograph measuring Aix was compared to other non-invasive methods as well. In Vienna Prof. Dr. Magometshnigg performed simultaneous measurements by applanation tonometer (SphygmoCor, Atcor, Australia) and TensioMed™ Arteriograph. As the invasive tests, this comparison provided similar results with very high correlation (R = 0,85).

Simultaneous measurements of AIx recorded by ARTERIOGRAPH vs SPHYGMOCOR



Magometschnigg, D.: WMW 2005, 155/17-18: 404-410

Not only the Aix, but the PWV has been validated invasively. In this respect TensioMed™ Arteriograph is the only device measuring arterial stiffness and complex hemodynamic parameters, which was tested against invasive PWV. In simultaneous measurements of 11 patients (invasive PWV versus the Arteriograph PWV) were carried out and the correlation proved to be excellent (R = 0,85).



A. Cziráki et al.: University of Pécs, Dept. of Cardiology, Pécs, Hungary

With the PWVao, beyond the invasive study, non-invasive comparison was also taken place at Bonn University (Medizinische Poliklinik). They concluded that "the new oscillometric method of assessing PWVao is highly correlated to the tonometrically derived PWV".

Probably the most reliable clinical test if the PWV values measured by the new oscillometric method correlated with the age, because it is well documented that the aortic PWV increases with age. Indeed, our study showed a similar significant increase of PWV with age, analyzing the PWVao of more than 2000 patients from age of 4 to 90.

Conclusions
From the reachable information that are in our hand we could define that **the uplifted Aix and PWVao** on the one hand are one of the already known classical risk factor's markers, on the other hand – and maybe it is more important thing – are independent from the **classical risk factors, self-dependent forecasts of the heart and vascular mortality**. An account of these the measurement of the Aix and the PWVao have very important information that couldn't be changed in the determination of the individual cardiovascular risk.

The Arteriograph makes an break through in the measurement of the arterial stiffness while now we have the possibility to measure non-invasively, simple, fast, user independent simultaneous the arterial stiffness (augmentation index (Aix), the aorta pulse wave velocity (PWVao). With these we have the key to the multitudinous, population's size secondary prevention medical check-up.

The examinations with the Arteriograph showed that with this simple method we could make the same examination with the same resolution on the pulse curve from the upper arm's artery as with a catheter in the vein.

The hermodynamical parameters which were measured by the Arteriograph

Sys - Systolic blood pressure *(Hgmm)*

Dia - Diastolic blood pressure *(Hgmm)*

HR - *Heart Rate –(rate/min)*

MAP *Mean Arterial Pressure(Hgmm)*
That calculated from the systolic and diasolic blood pressure.
MAP = diastolic blood pressure + (systolic – diastolic blood pressure)/3

PP-*Pulse Pressure (Hgmm)*
The PP is the difference between the systolic and diastolic blood pressure in Hgmm. If the value is over 60 than it means CV risk, especially if it beside normal or low diastolic pressure detected, because it relate to the aortic wall windbox function failure.

Aix brachial *(%)*
The augmentation index measured on the brachial artery by the Arteriograph. The calculation of the Aix was mentioned before in details.

Aix aortic *(%)*
The calculated value based on the correlation of the simultaneous measured aortic- and brachial Aix. The calculation software of the Arteriograph calculates the normal and the chronic limits on the base of the brachial Aix. We gives the aortic Aix

because the brachial calculation measurement results give the generaltransfer function of the devices of…

***ED** – left ventricle ejection time (Ejection Duration)*
The left ventricle Ejection Time (ED) by measuring the time between the opening and closing of the aortic valves. Which time decreasing by cardiac failure (decreased systolic volume and cardiac output).

***RT** - Return time*
The RT is the pulse wave velocity time from the aortic root until the bifurcation and return. This value is smaller as the aortic wall is stiffer. If we divide the measured RT (in sec.) value by two (one way velocity time between the aortic root and the bifurcation), as well we measure the distance in meter between the jugulum-symphisis, (which validly is the same as the distance between the aortic root and the bifurcation), than following the v=s/t equation we get the aortic pulse wave velocity (PWVao) in m/s dimension.

For example to be compareable with the values of the SphygmoCor.
The calculated values of the arteriograph and the SphygmoCor have a strong correlation, that we have already written in the section Validation.

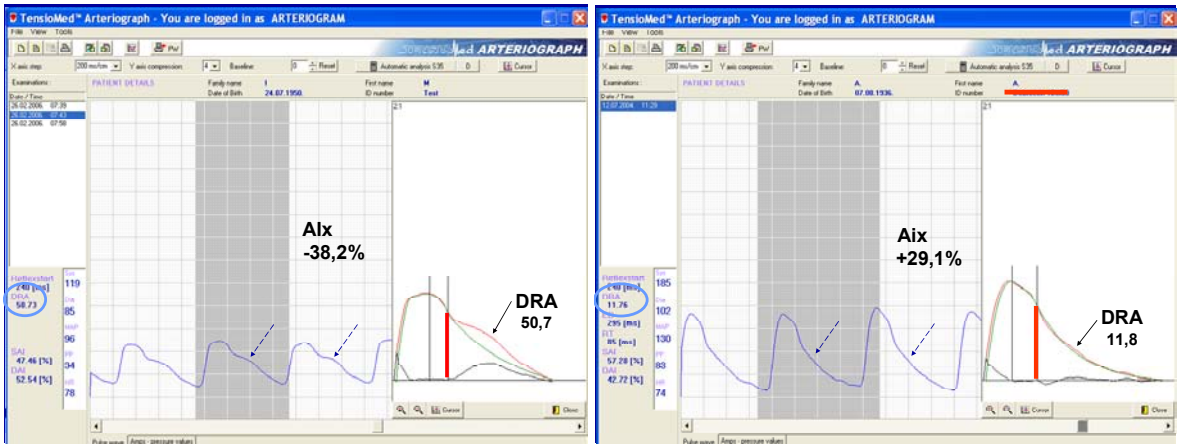
***PWVao** (m/s)*
The Pulse Wave Velocity (PWV) of the aorta.

***SD_{PWVao}** (m/s)*
It is a parameter about the quality of the measurement. It is the standard deviation of the detected cardiac cycles PWVao measured by the Arteriograph in suprasystolic range. Over 1.1m/s standard deviation on the display you can see a red warning message. It is because there are circumstances that disturb the measurement (e.g. motion, arrhythmic, respiration, etc.), disfigure the individual pulse waves and we have false values. Over 1.1m/s SD we have to repeat the measurement with stricter rules. The rules of the measurement can be seen in a later chapter.

***SBPao** (Hgmm)*
It is the systolic blood pressure which is in the aortic root. It is important because the systolic blood pressure measured in the aortic root in younger ages in case of elastic aortic wall is less than on the peripheral, on the upper arm. The difference between the central and peripheral systolic pressure called pressure amplification. Later the aortic wall elasticity going down as the people became older and because of this the pressure amplification going down progressively. So the systolic pressure progressively reaches the pressure on the peripheral.
By the treatment of the hypertonic patient it has a big importance that we also have to efficient decrease the peripheral blood pressure not just only the central blood pressure.

***DRA**- Diastolic reflection area (A value without a dimension)*
The method gives us information furthermore the quality of the coronaries diastolic filling. The examination of the correlation of the coronaries diastolic perfusion gives us the DRA. The method of the calculation is that on diastolic cuff pressure we take a

block from the recorded diastolic volume curves and the mathematical method that is built in the software calculates it from the systolic block if there weren't any wave reflection at the diastolic block. The DRA is the area of the limited block of the wave block without reflection and the real with reflection. As big is the DRA as better is the perfusion of the coronaries.



On the upper figures with a normal augmentation index a normotenison patient (on the left figure) and a hypertonic, endothel/vascular dysfunction's patient (on the right figure), a typical DRA can be seen. Beside the low (-38.2%) Aix the diastolic reflection marked the DRA value is over 50, while the high Aix (+29.1%) refer to vasoconstriction, in this case the diastolic reflection decreased greatly (DRA=11.8).

SAI – *Systolic Area Index (%)*
The area under the pulse wave curve of a single heart beat recorded at diastole corresponding to the systole time, which is a percent of the whole area under the curve.

DAI – *Diastolic Area Index (%)*
The area under the pulse wave curve of a single heart beat recorded at diastole corresponding to the diastole time, which is a percent of the whole area under the curve.
As big is the DAI as better is the perfusion of the coronaries.

The TL1 type TensioClinic device with the TensioMed™ software that running on an IBM-PC computer could measure during the blood pressure measuring time and with a programmable cuff on the cuff registering the pressure impulse created by the heart and to analyse the registered pulse wave shape and parameters. The TL1 type TensioClinic could be used as a normal blood pressure device. The blood pressure measuring function validated to the clinical and research ESH International Protocol 2002. The device determines the blood pressure value with an oscillometrical method.

1.2. Preliminary Information

It is recommended to read thoroughly this User's Manual and to take care especially of the following items during usage:

You should use only the prescribed Nickel-Cadmium (NiCd) or Nickel-Metal-Hydrid (NiMH) accumulators of capacity of at least 1500 mAh of type Mignon AA in the arteriograph of type TL1.

The apparatus may be also operated with long life disposable batteries of 1.5 V, size AA.

Attention! You should take out the batteries from the apparatus when it is out of usage for long time. We would like to pay your attention to keep the apparatus safely out of reach of children when it is out of use.

The apparatus must be used only with special supervision for patients suffering from heavy limitation of motion or inert patients, for patients having blood coagulation disorder, as well as for children.

Do not take off the cover of the apparatus. The apparatus TensioClinic is a measuring instrument based on sophisticated technology, applicable for a multitude of purposes and controlled by computer program. If any problem of functioning occurs, you should turn to a qualified service.

Caution! The device is a dangerous waste so if you don't use it any more please take of it. And in this case send it back to the producer!

1.3. The accessories of the apparatus

The accessories of the apparatus TensioClinic are as follows:

- 4 long life batteries of size AA
- an alternative cuff for adults
- a normal cuff for adults
- a cuff for children
- the program TensioMed™ on CD
- a measuring instrument to define the distance between jugulum and symphysis
- the User's Manual

The dimensions of cuffs are as follows:

	Dimensions of the inflatable hose	Total dimensions of the cuff	Circumference of the arm
Alternative for adults (Alternative adult)	35.4 × 12.7 cm	57.5 × 14.5 cm	34 - 42 cm
For children (Child)	19.1 × 10.2 cm	46 × 12 cm	20 - 30 cm
For little children (New size child)	20.2 x 9 cm	36.5 x 10.2 cm	15 - 25 cm

Note: It is essential to use the cuff of adequate dimensions to carry out measurements without disturbance and accurately.

Attention!
The apparatus is explicitly sensible to the usage of unnecessary large cuff!

YOU SHOULD ALWAYS MEASURE
WITH THE CUFF MARKED CHILD!
YOU SHOULD CHANGE TO A LARGER CUFF IF THIS ONE MIGHT NOT BE PUT ON THE UPPER ARM AT ALL!

WHEN YOU EXAMINE WOMEN, YOU MUST TAKE CARE
TO PUT THE CUFF EXPLICITELY TIGHTLY ON!

The program gives also warning message if the above mentioned problem occurs, because if the cuff is loose or too large, it warns that the pulse amplitudes are too small and it is unable to perform the automatic evaluation.

1.4. The operating switches and symbols on the apparatus and their meanings

The front view of the apparatus is shown in the Figure 1.

1 The name of the apparatus
2 Pushbutton to enter two commands to control the apparatus as described in the Chapter 1.6.
3 Symbols reminding to the above mentioned two commands as described in the Chapter 1.6
4 LCD display

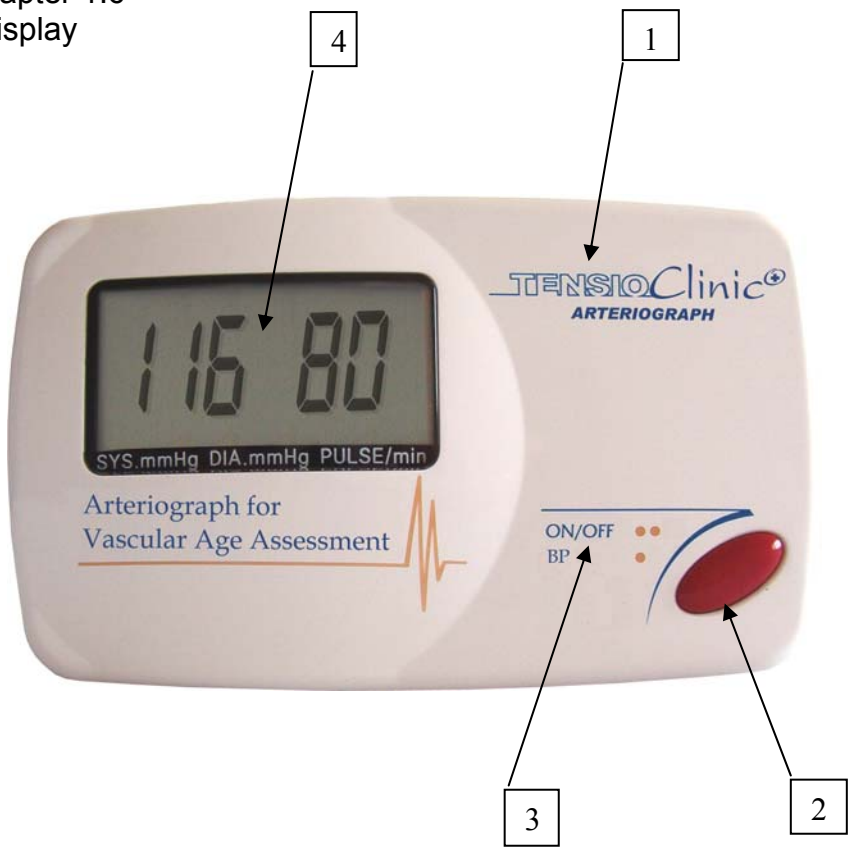


Figure 1

The symbols on the lower part of the apparatus are shown in the Figure 2.

5 The manufacturer's LOGO.
6 The name of the apparatus
7 The type number of the apparatus
8 The nominal voltage range applicable with batteries
9 The classification of the protection against electric shock. Classification: patient's side: BF.
10 Calling the attention to read thoroughly the present User's Manual.
11 Certification mark guaranteeing that the apparatus complies with the prescriptions and requirements of the European Union.
12 Serial number.
13 Operating ambient temperature range
14 Year of the manufecturing

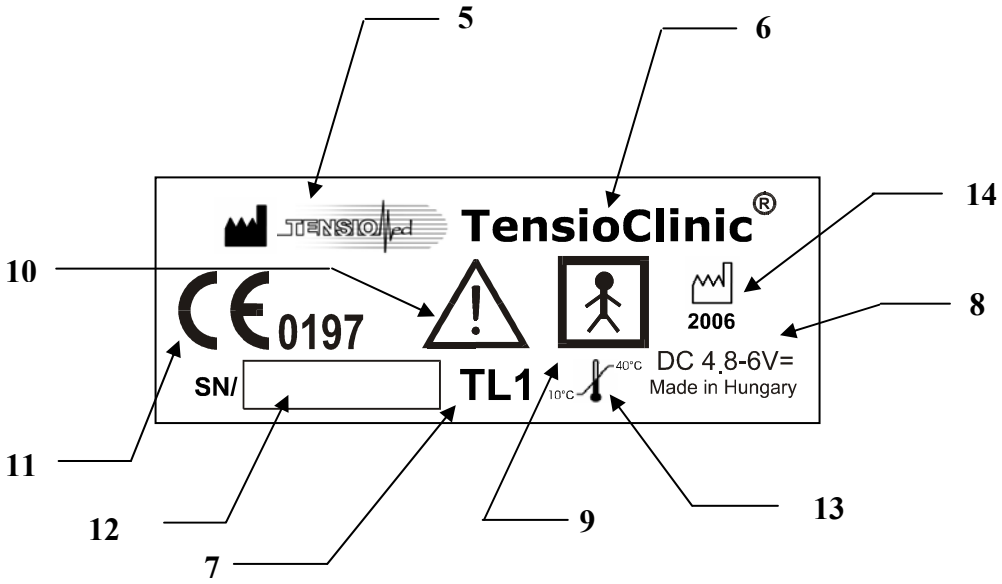
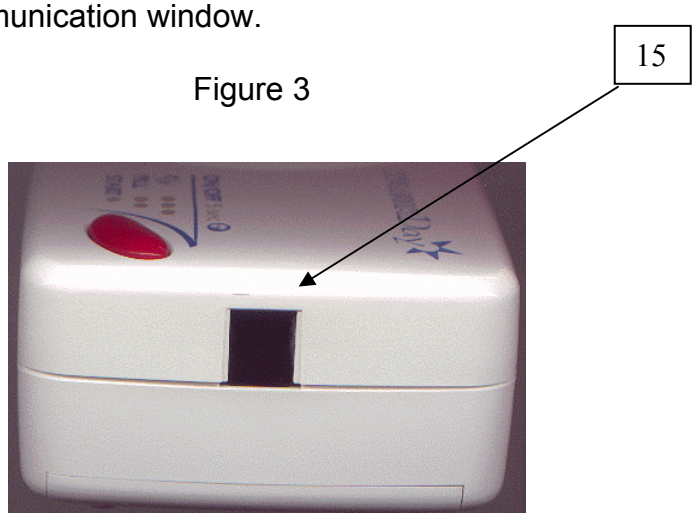


Figure 2.

The side view of the apparatus is shown in the Figure 3.
15 The infrared communication window.

Figure 3



1.5. Putting the apparatus into operation

The apparatus operates with batteries.

- Put 4 Ni-MH or NiCd rechargeable batteries of size AA into the apparatus with attention to the right polarity,
- or put 4 durable batteries of size AA as described above.
- The TensioMed Ltd. recommends usage of NiMH or NiCd rechargeable batteries of capacity of at least 1500 mAh for the adequate operation
- The recommended battery chargers are: ANSMAN 4T2, FRIWO or VARTA.

The Ni-MH or NiCd rechargeable batteries may be recharged about 1000 times depending on the manner of usage. When the batteries are discharged or their power is low, that is automatically indicated by the apparatus, you are requested to change all the four batteries, not only those you think exhausted.

The clock circuits of the apparatus operate from built-in battery cells of type NiCd HA 35, being continuously recharged by the batteries AA. The clock does not require resetting after battery change.

If you want put the apparatus out of usage for a long time, you should take the batteries out. They should be stored in a cool dry place. Do not expose the batteries to strong heat, because it may result in shortcut. There are detailed prescriptions for environment protection and for accident prevention relating to the usage and collection of refuses of both rechargeable batteries and alkaline ones. The user has to comply with these prescriptions.

The apparatus is connected with the computer by infrared communication. The manufacturer made all necessary settings of the communication adapter. If you have changed these settings for any reason during the usage, you should make the following steps: The **date transfer rate should be set to 115200 bps**. You can set it in the window of the infrared adapter handling program. The data transfer does not work properly at a lower speed.

Enable the infrared communication on the computer. When the apparatus occurs after these settings in the range of action of the infrared communication adapter in a distance not more than 1 m, the apparatus automatically establishes the connection with the computer. The usage of program TensioMed™ is, of course, necessary for data transfer.

Attention! It may occur that the data transfer fails even if the settings are adequate. Its cause is that the connection between the apparatus and computer is cyclically interrupted after a defined time then it is established again. The data transfer fails, if it is started when the connection is interrupted. You should take the apparatus out of the range of action of the infrared adapter of the computer, then wait for a short time (about ten seconds) then put the apparatus back into the range of action of the infrared communication adapter of the computer.

1.6. The operation of the apparatus

First you should check the proper power supply for the operation of the apparatus TensioClinic (see Chapter 1.5). There is only one pushbutton for the operation of the apparatus (see Chapter 1.4). The measured values and the information about the status of the apparatus are shown on the LCD display.

The patient can issue altogether two different commands to the apparatus with the pushbutton.

1.6.1. The functions of the button on the apparatus

If you put the batteries or accumulators into the apparatus, it performs automatically the following steps:

– It controls the voltage of batteries. The measured value appears on the display. If the power voltage is adequate, the measured value must be between 6.0 and 4.4 V. (The nominal voltage is 4.8 V for accumulators)

If the voltage is lower than 4.4 V, the batteries must be replaced. A sign warning for battery replacement appears on the display.

If you use long life batteries for the operation of the apparatus, the measured nominal voltage is 6 V. If the batteries must be replaced, the apparatus shows warning sign as mentioned above.

If the battery voltage is adequate, the apparatus is ready for measurements, which is indicated by the current time shown on the LCD display, which is the same as that on the computer.

1. One short pushing on the button starts the manual blood pressure measurement. Attention! The apparatus performs **only blood pressure measurement** in this case the AIX and PWV are not defined!

It may occur that manual blood pressure measurement becomes necessary during usage of pulse wave analyzer. You may start the manual (out of turn) measurement with a single short pushing on the button. The exact time disappears in this case and

the test pattern of the LCD appears on the display

then the battery voltage is controlled again (see the figure)

then the apparatus is calibrated with setting of the zero pressure (see the figure)

Then the measurement begins with inflation of the cuff, indicated by a triangle showing upwards with its peak (see the figure)

During deflation of the cuff a triangle showing downwards appears on the display, as shown in the figure on the right

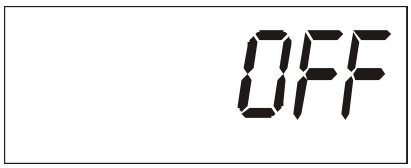
At the end of the measurement the apparatus displays the systolic and diastolic blood pressures.

then the pulse rate per minute appears on the display.

You can interrupt the measurement process at any time by a single short pushing on the button. The text "OFF" appears and remains about 10 seconds on the display (see the figure on the right). The time is displayed thereafter indicating the ready state of the apparatus for manual or programmed measurements.

The blood pressure measurement combined with pulse wave registration begins automatically under influence of the command issued by the program TensioMed™ running in a computer (PC) connected by infrared data transfer connection with the apparatus (it is not necessary to push the button!). The process of blood pressure measurement is exactly the same as described above. After the blood pressure measurement the apparatus measures the shapes of waves, which may be measured in the cuff, at the pressure and for the time defined by the program. The data of the pulse wave and the momentary pressure samples are transferred to the computer through the infrared data transfer and the change of pulse in the time may be followed on the display. The apparatus performs measurements at two previously defined pressure steps; they should be understood in relation to the currently measured systolic and diastolic blood pressures.

Two short pushes on the button switch the apparatus off. The double pushing on the button causes the text shown on the right to appear on the display. The above described single pushing on the button has no effect in this state. If you wish to use the apparatus again you should push the button twice again.
Under the effect of that command the text "OFF" disappears and all the functions of the apparatus are available again.



1.6.2. The data read out from the apparatus

The measured data are transferred to the computer through infrared communication. The following data are read out:

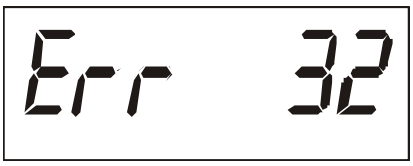
- The systolic and diastolic blood pressures (mmHg)
- The heart rate (1/min)
- The pressure in the cuff and its changes (in two channels) during the blood pressure measurement process i. e. a series of oscillometric impulses.

The infrared communication proceeds as follows: If an infrared communication adapter appears within the range of action of the apparatus, and it works i. e. it is enabled on the computer, the apparatus and the computer automatically connect. The text shown on the right appears on the LCD display in this case.
There is no effective data transfer yet, it may be started by the program TensioMed™.

While the infrared communication works between the apparatus and the computer, the signal shown on the right appears on the LCD display when actual data transfer goes on.

1.6.3. Error messages to user

The error codes and messages, which appear on the LCD and inform the user, are described below. It should be noted that you should not draw conclusions of a sole appearance of an error message, because the movement of the patient can simulate a multitude of errors. If the apparatus can not measure the blood pressure (e. g. because of the movement of the patient), the measurement is interrupted.



The meanings of the error codes issued by the apparatus are as follows:

1	"The measurement time is surpassed"	The apparatus could not measure the patient's blood pressure within the measurement time.
3	"The battery is down"	The measurement is interrupted because of the low charge of battery.

31	"The cuff is absent"	The cuff is not connected to the apparatus
32	"The cuff is blocked"	The rubber hose of the cuff is broken or foreign material e. g. water occurred in it.
33	"Leakage of air"	There is a leakage in the cuff (or in the apparatus).
34	"The cuff is not on the arm"	The cuff is connected to the apparatus but it is not put on the patient's arm.
35	"Measurement interrupted"	The measurement is interrupted in some reason, e. g. the patient pushed on the button.
90 to 99	"Error in the apparatus"	The blood pressure measurement failed because of the error of the apparatus or the charge of battery is low.
100	"Erroneous measurement result"	The measurement result may not be interpreted as real blood pressure or the patient may have arrhythmia.
110	"Erroneous measurement result"	The measurement result may not be interpreted as real blood pressure.
112	"Erroneous measurement result"	The measurement result may not be interpreted as real blood pressure or the patient may have arrhythmia.
111	"Erroneous measurement result"	The measurement result may not be interpreted as real blood pressure or the patient may have tremor (unintended rhythmical muscular movement)
113		
114		
115	"Erroneous measurement result"	The pulse rate may not be calculated or interpreted as real pulse rate.
101	"Movement"	The circumstances, e. g. the patient's movement disturb the measurement.
102	"No pulse sensed"	The apparatus does not sense the heart impulses in some reason.

1.6.4. Sound signals

The pushing of the button is accompanied always with small sound signal.

1.6.5. How to use the apparatus and how to perform a measurement

– **Put the smallest cuff (marked with CHILD) on the patient's dominant upper arm and stretch it as tight as possible. ATTENTION! You should use the smallest cuff even on adults!**

The apparatus is explicitly sensible to the usage of unnecessary large cuff!

YOU SHOULD ALWAYS MEASURE WITH THE CUFF MARKED CHILD!

YOU SHOULD CHANGE TO A LARGER CUFF IF THIS ONE MIGHT NOT BE PUT ON THE UPPER ARM AT ALL!

WHEN XOU EXAMINE WOMEN, YOU MUST TAKE CARE TO PUT THE CUFF EXPLICITELY TIGHTLY ON!

The program gives also warning message if the above mentioned problem occurs, because if the cuff is loose or too large, it warns that the pulse amplitudes are too small and it is unable to perform the automatic evaluation.

ASK THE PATIENT NOT TO BREATH DURING THE SYSPRASYSTOLIC (3rd INFLATION) PERIOD OF MEASUREMENT!

BY THIS WAS THE QUALITY OF THE RECORDING CAN BE IMPROVED, BECAUSE THE BREATHING CAUSED STROKE VOLUME CHANGES COULD BE ELIMINATED.

ATTENTION!
THE CUFF SHOULD NOT TOUCH THE PATIENT'S BREAST, BECAUSE THE MOVEMENT OF BREAST CAUSED BY THE RESPIRATION MAY CHANGE THE PRESSURE IN THE CUFF!

- You should put the cuff on with the rubber hose downward in the height of the artery brachialis. You should take care that the rubber hose does not hinder the free movement.
- In order to avoid irritation of skin a thin T-shirt or shirt may be worn under the cuff.
- Put the stud of the hose of cuff into the flatted black opening on the left side of apparatus. **Attention! You should take care that the connection of cuff should not be too loose**, it should not leak, so you should push the stud with energetic turning movements up to the stop into the opening.
- **Speaking, muscular movement, especially the movement of the muscles of**

the arm should be avoided during the measurement, because they significantly increase the time of measurement or may lead to failure of measurement, or diminish its exactitude. The movement of muscles distorts the shape of measured pulse wave and makes the evaluation impossible.

- **The patient should not eat a greater quantity, he or she should not drink black coffee, smoke in three hours and he or she should not drink alcohol in ten hours before the examination. The patient should not sleep during the measurement!**
- **The nitrates are those from among the medicaments, which exert the greatest influence on the measured values, because they cause strong dilatation both in the small arteries and in the larger ones of leading type, so they diminish the values of Aix and PWV in this way.**
- **A physical and psychical rest of at least 10 minutes is necessary before the measurement.**
- **All the circumstances should be avoided during the measurement, like opening of door, telephone call etc., which may disturb the patient's complete quietness,**
- **If you perceive white coat effect, you have to repeat the measurement several times after some minutes' pause.**

1.7. Further characteristic data and recommendations

- The apparatus does not produce electromagnetic disturbance during operation, as well as its shielding against the disturbances of environment is adequate. The measured data are read into the attending physician's computer through optical infrared communication. The electromagnetic compatibility between the apparatus and the computer is guaranteed. The EMC classification of the apparatus is A.
- In order to ensure the optimal performance and exact function, it is recommended to perform maintenance by our specialized service station at least once in two years.
- The cuff and the apparatus may be cleaned with wet wiper taking care that no liquid enters the apparatus.
- The manufacturer's products are handled, stored, packed the conservation of status and shipments are performed complying with the general requirements of preserving quality.
- The apparatus complies with the prescriptions of the following norms:

EN 60601-1:1995+A1:1993+A2:1995+A13:1996 General safety requirements,
EN 60601-1-2:2001 Electromagnetic compatibility,
EN 1060-1:1995+A1:2002 Non-invasive blood pressure meters - Part One: General requirements,
EN 1060-3:1997 Non-invasive blood pressure meters - Part Three: Complementary requirements,
MSZ EN ISO 14971:2000 Tools of medical technology. Application of risk direction to tools of medical technology,
93/42/EEC Guiding rule Medical Tools: 1993, ESH International protocol 2002

1.8. Addresses and phone numbers important to the user

The manufacturer, seller and repairer of the arteriograph TensioClinic, TensioMed™ is:

TensioMed Ltd.
Kőér str. 2/D, H-1103 Budapest, Hungary
Phone: (+36 1) 433 1700, 433 1701
Fax: (+36 1) 433 1709
E-mail: info@tensiomed.com

1.9. Guarantee:

The TensioMed Ltd. guarantees the apparatus for two years. This guarantee does not relate to the notebook computer given to the apparatus, because its manufacturer guarantees it. The TensioMed Ltd. makes all repairs within the period of guarantee and over it in its above mentioned plant.

2. The program TensioMed™

2.1. Preliminary information about the program TensioMed™

The software TensioMed™ consists of two components:

- The first component is the patients'- and the users' database. The patients' database is common, but each user can access the data of patients, whom he or she registered.
- The second component is specific part of the program TensioClinic serving to the setting of the apparatus and to read and analyze data of the measured pulse wave and those of blood pressure measurement.

2.2. The installation and starting of the program

Minimal requirements to the system

- A computer with processor Pentium IV, 256 MB of storage, 2 GB of free space on HDD, CDROM drive, display of resolution 1024*768 pixels,
- Windows XP operational system with Service Pack 2
- Active infrared port.

The program starts, of course in a poorer environment, but in this case there is no guarantee for the quick and reliable operation.

The installation

The program is installed and all its settings are done by the manufacturer.
If the program should be newly installed, you should do the following steps:
Insert the CD into CD drive of your computer. The installing program starts automatically! If it is not the case, you can start it by double-clicking to the program **setup.exe** on the CD. The setup program offers the default folder for the program TensioMed™. You can change it using the function Browse. Please wait while the program copies the files into the folder. The icon TensioClinic appears at the end of installation on the Desktop of the computer.

Starting the program

To start the program click double to the icon TensioClinic. At the first start the program does not request login name for logging in, but admits the user to log in with the default name "ARTERIOGRAM". The user name should be entered at all following logins. When an erroneous or not registered login name is entered, the program always offers the default one.

2.3. The menu items of the program

1. The menu File

You can use the basic functions of the program TensioMed™ using the **File** menu. You can register a new patient, change data already registered in the database, save new results of examinations, edit or print a medical report, to send it in e-mail or PDF-format and exit from the program.

2. The menu View

The menu View enables you to move among information items appearing on the graphic surface of the main window provided with millimeter net, to set a scale, to hide a toolbar or to look at the data of a currently chosen patient.

3. The menu Tools

The menu Tools enables you to start an automatic pulse wave data collection with the apparatus TensioClinic. You may also interrupt the measurement and data collection, which is going on. The settings of the program and the apparatus are also accessible from this menu.

2.4. The toolbar of the program

The toolbar may be displayed or hidden by the command Toolbar of the menu View.

You can key in and put data of a new patient into the database in the opening dialog box. It is equivalent with the command New patient of the menu **File**.

This tool displays the list of patients already entered in the database. It enables also to change the already existing data. It is equivalent with the command Open of the menu **File**.

This tool enables to save data after examination with the apparatus TensioClinic. It is equivalent with the command Save of the menu **File**.

This tool enables to print or to display the preview of the ready medical report. It is equivalent with the command Print preview and print of the menu **File**.

This tool enables to save the results after examination. It is equivalent with the command Save results of the menu **File**.

This tool enables to edit a medical report. It is equivalent with the command Edit report of the menu **File**.

This tool enables also to display the pressure in the cuff registered during the measurement as function of time in a window with millimeter net.

This tool enables to initiate an automatic measurement and data collection with the arteriograph TensioMed™. It is equivalent with the command PW read of the menu **Tools**.

X axis step:
With this tool you can set the scale of the horizontal, time axis of the of the pulse wave displayed on the millimeter net from 10 ms/cm to 1600 ms/cm in previously defined steps.

Y axis compression:
With this tool you can set the compression of the vertical, amplitude axis of the pulse wave on the millimeter net. Its value means the vertical compression of the curve. If it is one, the curve is displayed in the whole height.

Position of the base line:
With these buttons you can shift the pulse wave curve upwards or downwards in relation to the zero line. You can reset the original position with click on the button Erase.

This button starts the automatic analysis of the waves registered in the supra-systolic range. In this process the apparatus analyses individually the pulse wave curves corresponding to individual heart beats recorded at the pressure step of the measured systolic one + 35 mmHg and displays the obtained results after counting the average values. The following indexes will be calculated during the analysis:

- Aix brachial
- Aix aortic
- ED
- RT
- PWVao
- SD_{PWVao}
- SBPao

This button starts the automatic analysis of the waves registered in the diastolic range. In this process the apparatus analyses individually the pulse wave curves recorded at the pressure level corresponding to the currently measured diastolic pressure, and displays the obtained results after counting the average values. The primary pulse wave of the heart beat and the first and second reflected waves are extracted from the oscillation curve by decomposition.

The following indexes will be calculated during the analysis:

- DRA
- SAI
- DAI

The indexes which were displayed we mentioned before.

The display cursor may be turned on only when the scale of the axis X is set to 200 ms/cm. With the cursor you can take the coordinates of points of the pulse wave and the pressure curve respectively.

These buttons serve to move the cursor with short or long steps respectively.

2.5. Other handling tools

The button Interrupt appearing during the communication with the computer has the same function as the command Abort of the menu Tools.
You can roll the content of a window with the horizontal and vertical roll bars if they are enabled.

The handling tools listed below appear in a newly opened window only if an oscillation curve corresponding to only one heart beat was analyzed either in the supra-systolic range or in the diastolic one independently of the method of analysis (automatic or manual marking).

These buttons serve to magnify or reduce the analyzed wave appearing in the separate window.

This button enables to switch on a separate cursor in the window to the analyzed waves.

These buttons serve to move the cursor switched on by points in small steps.

Close, this button enables to close the window showing the analyzed curve.

2.6. The usage of the program

2.6.1. The users' data

Registration of a new user

If you are the sole user of the software TensioMed™, you may use the identifier "ARTERIOGRAM" offered by the program as default and do not need to enter any other user identifier.
If more than one user uses the program, to whom separate groups of patients belong, it may be necessary that after entering the program each user could reach only the data of his or hers patients. For this purpose the new user must be registered through his or hers name and identifier into the database. You can make the registration with the command Options of the menu Tools by clicking to the tab Users in the appearing dialog box. To enter a new user, click on the button New, then type the name and identifier of the user. You can save the registered new user in the database by clicking onto the button **OK**. The new user can enter the program with the new identifier.
Attention! It is not allowed to change the data of the registered users.

Erasing a registered user

To erase a user you should choose the command Options of the menu Tools and click onto the tab Users in the appearing dialog box. The element selected from the list of users may be erased by clicking onto the button Delete. If only one user is present in the list, this function is unavailable.

2.6.2. The patients' data

Choice of a patient

Having entered the program you can open the patients' list belonging to the user ID used for entering either by the command Open of the menu **File** or by clicking onto button Open of the toolbar. The list of patients appears. Seek for and choose the patient (with double click or by pressing on the button **OK** after marking). The name, birth date and identifier of the chosen patient appear under the toolbar. The examinations of the patient appear also in a list if they are present.
Note: If you have a great number of patients, you can find a certain patient using the function Search key. You may search for a patient by the name or the identifier. For the search by name you should mark the inscription Name at the field and type the name in. The search function may be used by entering a part of the name, as well.
Entering the patient's data

If you wish to enter data of a new patient into the database, you should choose the command **New Patient** of the menu **File** or you should click onto the button **New Patient** on the toolbar. To enter a new patient it is obligatory only to input an identifier and the birth date. It is advantageous to input the distance between the jugulum and

symphysis, what you can measure with the measuring instrument given as accessory to the apparatus. **It is necessary for the calculation of the pulse wave velocity.**
After input of the necessary data i. e. age, cholesterol level, smoker or non-smoker state, sex, and the risk estimating table it is possible furthermore to define the risk of occurrence of fatal cardiovascular events for the next ten years for the patient after each examination. There are two risk estimation tables used in Europe to estimate the risk. **Belgium, France, Greece, Italy, Luxembourg, Switzerland and Portugal belong to the countries of low risk. All the other European countries are regarded as those with high risk.** The estimated risk appears in the printed medical report, with a short evaluation:
The risk is:

1 high, if it is > 5 %
2 medium if it is ≤ 5 % and > 2 %
3 low, if it is ≤ 2 %

Other risk factors, which can also increase the estimated risk:
- Triglyceride, low HDL-C, diminished glycose tolerance (IGT), obesity, C-reactive protein (CRP), fibrinogen, homocystein, apo B, Lp/a,
- Positive familial cardiovascular anamnesis,
- Pre-clinic atherosclerosis (proved by examinations of electron beam [EB], CT, UH, MRI).

If you have defined an arbitrary new parameter e. g. body height [cm] using the options available by choosing the command **Options** in the menu **Tools**, you can put in its value in this dialog box, as well.
You can save the data by pressing on the button **OK**.

Change of patient's data

Choose the patient, whose data you wish to change. You may do this by one click in the patients' list, then push on the button Edit. It is not allowed to change the identifier.
You can save the modified data by pressing on the button **OK**.

2.6.3. Programming of the arteriograph TensioMed™

To enter settings of the apparatus you should choose the command **Options** of the menu **Tools**.
You may make the following settings on the tab System in the appearing dialog box:
- **Initial inflation pressure** i. e. the pressure, to which the arteriograph TensioMed™ inflates the cuff first at the beginning of the measurement. It may be a fixed value or a variable one. In the latter case the apparatus adds 35 mmHg to the last measured systolic pressure and it inflates the cuff to this pressure. The default setting is the variable value.
- **Offset of systolic pressure level** is the supra-systolic pressure step, where the apparatus collects pulse wave data. The default setting is 35 mmHg, i. e.

data are collected at the pressure above the currently measured systolic value by 35 mmHg. It is not advisable to deviate from this value in diagnostic examinations.

- **Offset of diastolic pressure level** is the pressure step around the diastole, where the apparatus collect pulse wave data. The default setting is 0 i. e. data are collected at the pressure step corresponding to the currently measured diastolic pressure. It is not advisable to deviate from this value in diagnostic examinations.
- **Data transfer time at dia and sys pressure level** are the time periods of data collection at the above defined pressure levels in seconds. The default setting is 8 sec. It is allowed to deviate from these values in the interval from 7 to 12 sec.
- **Update the calendar and clock of the device**. If it is chosen, the current date and time are downloaded from the personal computer into the apparatus. It is chosen at the default setting.
- **You can insert an arbitrary new parameter among the data of patient** in such a way that you type it in the offered input field – e. g. body height [cm] -, which appears in the same form as in the printout. You should press on the button **Set** to save the new parameter. You can enter only once a new parameter to a database of registered data! Having saved the new parameter, it appears in the parameters of patients either you enter data of a new patient or modify them of an already registered patient. The new parameter appears among the registered ones and you can enter its value.

You can access the default settings by clicking on the button **Default settings**. They should be downloaded separately into the apparatus. You should use the button **Download into the device** for this purpose.
The infrared window of the apparatus and that of the infrared communication adapter of the personal computer must be positioned oppositely. You should take care that no obstacle stood in the way of the infrared ray and that the windows should be on the same height. The distance between the apparatus and the computer must not be more than 1 m.
The loading of settings into apparatus can be followed on the display. The inscription "CO PC" is shown on the LCD during the communication (see Chapter 1.6.2.). The successful download is confirmed.

Settings, which are not specific to the apparatus:

- **The program language** You can choose the language of the program TensioMed™. If you change the language, you have to restart the program.
- **The date format.** You can choose from three formats: year-month-day, day-month-year or month-day-year.

The settings downloaded into the apparatus cannot be revoked. They may be changed only by reprogramming. You may approve the settings not specific to the apparatus by pressing on the button **OK.**

2.6.4. Examination with the arteriograph TensioMed™

You should either register a new patient or choose one from among the registered patients for the examination. Put the cuff on the patient and position the apparatus with its infrared window towards the infrared port of the personal computer. The distance between the apparatus and the personal computer must not be more than 1 m also during examination. Choose the command **PW read** in the menu **Tools** or press on the button **PW** on the toolbar. The communication process may be followed on the display. The inscription "CO PC" appears on the LCD display of the apparatus (see Chapter 1.6.2.) during data communication. After a short period of waiting a blood pressure measurement starts automatically with the primary aim to define the exact values of the systolic blood pressure and the diastolic one. The program registers the pulse wave curves during the measurement, which you can follow on the display. The apparatus inflates then the cuff to the measured diastolic pressure thereafter and registers the pulse waves during 8 seconds. The apparatus inflates then the cuff above the measured systolic pressure by 35 mmHg and also registers the pulse waves during 8 seconds at this pressure step. These values may be changed at the settings of the system as described above. At the end of examination the apparatus sends also the measured blood pressure values to the personal computer. The software displays the values of the systolic pressure, the diastolic one, the pulse frequency, MAP and the pulse pressure, as well as the registered pulse waves. If the examination is accomplished successfully, you can save the new data by the command Save of the menu **File** or by clicking on the button **Save** of the toolbar, the data are inserted into record according to date and time. You can delete the data of an examination after marking it in the list of examinations and pressing on the button **Delete** of the keyboard.
The examination may be interrupted by the command **Abort** of the menu **Tools** or by clicking on the button **Abort** appearing during the data transfer on the bottom of the program window. You should also press once on the operating button of the arteriograph TensioMed™ at the same time (see Chapter 1.6.1.).

2.6.5. The analysis of the data

Choose a patient and the one of his or hers examinations, which you wish to evaluate. You have two ways for evaluation: automatic and manual.

The first one provides quick and comfortable usage. The automatic evaluation will be executed after a click on the selected patient data. The same will happen after a click on the button **Automatic analysis S35** then after the appearance of results you should click on the button **D.** The above described parameters appear in the program window under the list of examinations. During the automatic analysis the algorithm analyzes several (at the diastolic pressure step, however, only three) pulse waves belonging to heart beats, and counts the average values of the results. If only one pulse wave of a heart beat was successfully analyzed either from the pulse waves recorded at the supra-systolic pressure step or from those recorded at the pressure step near to diastolic one, the sole analyzed wave appears in a window opening on the millimeter net.

Accordingly, the opening window may have content of two different types:

- The sole real pulse wave curve registered at the supra-systolic step, drawn with green line, found by the algorithm and displayed after elimination of the distorting effect of the signal transferring electronic apparatus. There are four marks on the curve indicating from left to right: the location of the highest point of the main wave, those of foot point and the highest one of the first reflected wave respectively, where RT is the time between the beginning of the main wave and the foot point of the first reflected wave, as well as the end of signal change after the first reflection, i. e. the closing of the aorta valve, the ED value. It may occur in some pathologic cases that the foot point of the first reflection precedes the highest point of the main wave, i. e. the reflected wave arrives earlier than the main wave reaches its highest point.
- The sole pulse wave registered at the diastolic pressure step drawn with red line found by the algorithm, which may be evaluated, and the components of this curve: the main wave and the first reflected wave, drawn with green line, which usually merge in the case of curves measured at this pressure step and the second reflected wave drawn with black line. There are two marks on the curves, which indicate from left to right: the location of the of the highest point of the main wave and that of the beginning of the second reflected wave.

The curves may be enlarged or reduced in size within previously defined limits (see Chapter 2.5.), the value of the enlargement or the reduction respectively appears in the left upper corner of the window. You can also to examine the curves from point to point using a cursor, which you may switch on.

If you wish to make **manual evaluation**, you should first go to the end of registered curves, you can do it using the horizontal scroll bar on the bottom of graphic area. The curves recorded at supra-systolic pressure are at the end of the complete record of curves, the ones recorded at diastolic pressure precede them. You can mark an arbitrarily chosen sphygmogram belonging to a heart beat from among the curves recorded at the above mentioned both pressure steps. To do this you should keep pressed the button of the mouse while you move it. The results are display in the same way as described at the automatic analysis in the case when one curve was found.
You can save the evaluation results by clicking on the button **Save results** or by the command **Save results** of the menu **File** into a text file for further processing. The text file has the name of the file of registered curves as first part completed with the suffix "_Data". Only one result file belongs to an examination, but the file may additionally contain saved results produced by later analyses.

Notes:
You may mark several successive curves with the mouse. If the program can analyze all of them, it does not open a separate window, it displays only the average values of results in the usual way. If the analysis of only one curve is successful, it displays that curve also in a separate window.
You may mark curves from those of waves recorded during blood pressure measurement, but only from among those, which were recorded at the pressure steps either above the measured systole or at the measured diastole ±10 mmHg. To display the pressures you should press on the button **View the pressure curve** of the toolbar. You can read exact values using the cursor. Curves recorded at different

pressure steps might not be analyzed in one operation!

2.6.6. Editing save and printing a medical report

The functions are available, after you have chosen a patient and one of his or hers examinations. To edit a medical report you should click on the button **Edit report** on the toolbar or choose the command **Edit report** of the menu **File**. You can prepare the report in the opened window, and you may archive its content by clicking on the button **Save**. The edited report appears on the second page of the printout.

You can print a medical report with the command **Print preview and print** of the menu **File** or by clicking on the button **Print preview and print** on the toolbar. The printed report contains the following data:

- **The patient's data.** The data recorded at the entering of the patient are shown here. If the data are sufficient (see Chapter 2.6.2 The Patient's data) the calculated risk of fatal cardio-vascular events within ten years for the patient, as well as a parameter set by the user and its value, if available, are also shown. The places of data, which are absent, remain empty.
- **The parameters of the examination.** This part contains the date and time of the completed examination, the name of the person accomplishing the examination, the parameters of blood pressure and the distance from jugulum to symphysis (JUG-SY) if it is recorded.
- **Results at S35.** This part contains the parameters resulting from the analysis of pulse wave curves recorded at the supra-systolic pressure step, complemented with a section of pulse wave curves and the average of the analyzed curves. In this latter case only the locations of the foot point of the reflected wave (**RTS35**) and the **ED** are marked.
- **Results at D.** This part contains the parameters resulting from the analysis of diastolic pulse wave curves recorded at the diastolic pressure step, complemented with a section of pulse waves (if more than one curve was marked for analysis, the last one). The parameters **DRA**, **SAI** and **DAI** may be defined only if a previously defined **ED** is available.
- **Automatic analysis.** The program orders the values of the brachial augmentation index (Aix brachial) and the aortic pulse wave velocity (PWVao) into ranges as follows:

AIX < -30 %	**optimal**
-30 % ≤ AIX < -10 %	**normal**
-10 % ≤ AIX ≤ 10 %	**elevated**
AIX > 10 %	**pathologic**

PWVao < 7 m/s	**optimal**
7 m/s ≤ PWVao < 9.7 m/s	**normal**
9.7 m/s ≤ PWVao ≤ 12 m/s	**elevated**
PWVao > 12 m/s	**pathologic**

Note:
It is a parameter about the quality of the measurement. It is the standard deviation of

the detected cardiac cycles SD_{PWVao} measured by the Arteriograph in suprasystolic range. Over 1.1m/s standard deviation on the display you can see a red warning message ***SD_{PWVao}***. It is because there are circumstances that disturb the measurement (e.g. motion, arrhythmic, respiration, etc.), disfigure the individual pulse waves and we have false PWVao values. Over 1.1m/s SD we have to repeat the measurement with stricter rules. The rules of the measurement can be seen in a later chapter.

- **The edited medical report (on the 2nd page)**
- **The date and time of printing** complemented with the **serial number of the apparatus** used for the measurement and with the **number of measurements** made by the apparatus up to this one.
- **Information about the manufacturer** complemented with the **version number of the evaluating software.**
- **Data of the institute:**

  In order to show data of the institute in the printed report, you should choose the command **Settings** of the menu **Tools**. You can enter the following data on the tab **Printed report** in the appearing dialog window:
  - The physician's registered data
  - The data of the institute

  From among these data the last ones appear completely, from among the physician's registered data only the name and the seal number appear in the footing of the printed medical report.

Note:
The medical report will be always printed in A4 format. It contains always so much information as given or defined during the analyses. This means that you can even print a report, which contains only the patient's data.

The limit values are compiled on the base of the medical literature specialized on the arterial age and our own experiences.

You have the chance to save the medical report into a file. Click at the print preview window on the **Save report** button. The file name will be by default the patient name plus the actual date and time. You can change it if you want. The place of the save by default is the place where you have saved the actual patient's measurements data. You can set and display the actual patient's saved medical reports at the print preview window by clicking on the **Load report** button.

2.6.7. Sending a medical report in PDF format

You can convert the above described medical report with the command **Send PDF report** of the menu **File** into **format PDF and simply send it by e-mail**. Having chosen the command the program converts the above described medical report into PDF format, which appears in the folder Records under the file name:

Tcrep_ patient's ID_date according to the chosen date form_examination time.pdf

If you have a previously set default correspondence program available on the computer, it is automatically called and you should only fill out the address field and write in the text of the letter.

3. Technical characteristics

Power supply:
4 rechargeable accumulators or long life alkaline batteries of size AA
Protection against electric shock:
The apparatus is powered internally with batteries
Shockproof category:
Type BF on the patient's side
Display:
Liquid Crystal Display (LCD)
Data storage:
EEPROM
Data transfer:
Optical, IrDA, 115200 bps
PC interface:
Infrared communication adapter
System requirements to the personal computer:
Windows XP with Service Pack 2
Environment temperature:
10 to 40 °C
Environment humidity:
30 to 85 %
Dimensions:
128.0 x 77.5 x 45.5 mm
Weight:
310 g
Method of blood pressure measurement:
Oscillometric measurement
Sampling frequency:
200 Hz
Limits of blood pressure measurement:
30 to 280 mmHg
Static accuracy:
±3 mmHg or ±2 % of the measured value (stability: 2 years)
Accuracy of measurement (ESH International Protocol 2002):
At systole: *91 of 99 comparisons (91 %) is within 5 mmHg,* *2 of 3 comparisons done at 33 of 33 patients was within 5 mmHg,* *No patient was from among 33 to whom no measurement of 3 was within 5 mmHg* *At diastole:* *97 of 99 comparisons (98 %) was within 5 mmHg,* *2 of 3 comparisons done at 32 of 33 patients was within 5 mmHg,* *No patient was from among 33 to whom no measurement of 3 was within 5 mmHg* *Average deviation from the auscultational (Korotkov's) measurements:* *(at systole/diastole): 0.4/-0.3 mmHg* *Dispersion of the deviation (at systole/diastole): 2.7/2.3 mmHg*
Pressure sensor:
Piezo-resistive
Inflation:
With automatic power-driven pump
Safety:
The highest pressure in the cuff is 280 mmHg
Deflation:
Automatic
Working method of the apparatus:
Continuous

4. Intellectual property

The apparatus and method of the arteriograph of type TL1 are intellectual property of dr. Miklós Illyés and Mr. József Béres and they are protected by Hungarian patent application of application No. HU P0400426. The software TensioMed™ is a product developed by the TensioMed Ltd. All rights are reserved.